

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-13, 15-25 and 53-56 are in this case. Claims 1-13, 15-25 and 53-56 have been rejected under § 102(b) or § 103(a).

Independent claims 1 and 13, and dependent claims 4-6, 8, 9, 16-18, 20 and 21 have now been amended. Dependent claims 7 and 19 have now been canceled. As a result of these amendments, the claims pending before the Examiner will be claims 1-6, 8-13, 15-18, 20-25 and 53-56.

§ 102(e) & § 103(a) Rejections

The Examiner has rejected claims 1 and 10-11 under 35 U.S.C. 102(e) as being anticipated by Trautman et al. (US2002/0032415). The Examiner has also rejected claims 2-4, 7, 8, 13, 15-17, 19, 20, 22-24, 53, 54 and 56 under 35 U.S.C. 103(a) as being unpatentable over Trautman et al. in view of Olson (US 6,749,792). The Examiner has additionally rejected claims 12 and 25 under 35 U.S.C. 103(a) as being unpatentable over Trautman et al. (or Trautman et al. in view of Olson) in view of Avrahami et al. (US2002/0038101). The Examiner has also rejected claims 9 and 21 under 35 U.S.C. 103(a) as being unpatentable over Trautman et al. in view of Olson in further view of Palasis et al. (US 6,319,230). Finally, the Examiner has rejected claims 5, 6, 18 and 55 under 35 U.S.C. 103(a) as being unpatentable over Trautman et al. (or Trautman et al. in view of Olson). The Examiner's rejections are respectfully traversed.

Trautman et al. discloses a device and method for enhancing skin piercing by microprotrusions to form pathways through the skin. A drug is then delivered to the body surface for transfer through the microcuts (paragraphs [0064] and [0065]).

The microprotrusions of Trautman et al. are formed as a pattern of saw-tooth projections cut from a metal sheet preferably of thickness 25-50 microns (paragraph [0046]). The resulting microprojections, referred to as "microblades" (e.g., page 9, left column, line 20), are highly suited to directional sliding insertion into the skin, providing effective penetration and low resistance so as to cut thin "microcuts" or "microslits".

Olson discloses various structures of hollow microneedles which incorporate fluid flow conduits such that each microneedle samples fluids or delivers a drug through its included conduit. The overall profile of the microneedles of Olson is generally conical.

Referring specifically to the rejections of claims 7 and 19, the Examiner has stated that *"it would have been obvious to use the microneedles of Olson with the system of Trautman et al. in order to optimize the needle structure for maximal drug delivery or fluid removal."* In response, the Applicant respectfully disagrees.

Firstly, the Applicant points to the clear implication throughout the Trautman et al. document that flat microblades are the appropriate configuration for use in a sliding motion to form microcuts. A person having ordinary skill in the art and familiar with the Trautman et al. document would reject the possibility of using a hollow microneedle structure since the necessary increase in dimensions perpendicular to the direction of motion would prevent the microneedles from providing the microblade functionality required by Trautman et al.

Secondly, the round conical forms of microneedle taught by Olson clearly lack the geometry required for sliding penetration into the skin. The round sides of the conical forms would aggravate the exact problem which Trautman comes to address, namely, the tendency of the skin to flex around microprojections rather than be pierced.

In contrast, the present invention provides structures and methods in which microneedles with fluid flow conduits achieve enhanced penetration into the skin by insertion through a motion with a component parallel to the skin. This is achieved by employing microneedle structures which provide lateral cutting edges (cf. dependent claims 4-6, 16-18 and independent claims 53 and 54).

While continuing to traverse the Examiner's rejections, the Applicant has, in order to expedite the prosecution, chosen to amend independent claims 1, 13, 53 and 54 in order to clarify and emphasize the crucial distinctions between the device of the present invention and the device of the Trautman et al. and Olson patents cited by the Examiner. Specifically, claims 1, 13, 53 and 54 have been amended to clarify that the microneedle structures include a conduit extending through at least part of the microneedle and configured to provide a fluid flow path for transport of fluids, thereby explicitly excluding the use of flat microblades as taught by Trautman et al. Regarding the combination of Trautman et al. with Olson, the Applicant respectfully submits that this combination is improper, due to the apparent incompatibility of the teachings of the documents, as already discussed above.

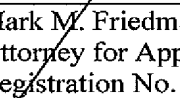
Support for these amendments can be found in the specification, and particularly in claims 7 and 19 (now canceled) as filed.

Amended independent claims 1, 13, 53 and 54 now feature language which makes it absolutely clear that the device of the present invention employs

microneedles with included fluid flow conduits in an insertion motion with a component parallel to the skin. The Applicant believes that the amendment of the claims completely overcomes the Examiner's rejections on § 102(e) and § 103 grounds.

In view of the above amendments and remarks it is respectfully submitted that independent claims 1 and 13, and hence also claims 2-6, 8-12, 15-18 and 20-25 which depend therefrom, are in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



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